SUMMARY OF THE PROFICIENCY TESTING COMMITTEE MEETING NOVEMBER 9-10, 1998

The Proficiency Testing Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Monday and Tuesday, November 9-10, 1998, in Norfolk, VA. The meeting was led by its chair, Ms. Anne Rhyne of the Texas Natural Resource Conservation Commission. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The principal purpose of the meeting was to discuss unresolved issues and to prepare for the NELAC IV Interim Meeting in January, 1999.*

INTRODUCTION

Ms. Rhyne began the meeting by introducing members of the committee and reviewing the meeting agenda. Also in attendance were Mr. Bob Graves and Ms. Elizabeth Dutrow from the U.S. Environmental Protection Agency (EPA). Ms. Reenie Parris from the National Institute of Standards and Technology (NIST) also joined the meeting briefly by telephone in order to update the committee on the status of NIST's accreditation program for proficiency testing (PT) Providers, and to answer questions.

Committee members reviewed comments (received from the Environmental Laboratory Advisory Board [ELAB], Tom McAninch from Eastman Kodak, the Virginia NELAC Workgoup, and Barry Detrick from Suburban Water Testing Laboratories) and presented responses and/or suggested changes for their assigned sections of Chapter 2. The primary changes to the chapter and related discussions are summarized below.

Chapter 2, Sections 2.0 - 2.3 (Cindy Nettrour)

PT Fields of Testing

The committee agreed that clarification was needed in **Section 2.1.3**. They elected to delete the second sentence in 2.1.3, "Laboratories may choose to participate in one or more PT fields of testing." In order to provide clarification, text from **Section 2.5** was moved to **Section 2.4.1** which now begins, "To be accredited initially and to maintain accreditation, a laboratory shall participate in two single-blind, single-concentration PT studies, where available, provided by a PTPA-approved PT provider per year for each field of testing for which it seeks or wants to maintain accreditation (described in Chapter 1)." More discussion on PT fields of testing and scope of accreditation is under the section entitled "Unresolved Issues" of these minutes.

Analyte List

Section 2.3.2.1 states that "within each study, a certain minimum number of analytes shall be present. The group of analytes included shall change over time so that all analytes are included at least once every three years over a series of sequential studies." An analyte list or other clarification was requested by commentors. The committee agrees that clarification is needed, but

has not yet resolved this. Ms. Nettrour will draft some proposed language and send it out to the committee (copy to Mr. Graves) for review and suggestions.

<u>List of Approved PT Providers</u>

Section 2.3.7 previously stated that the Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA) would publish a list of approved PT providers at intervals not to exceed six months. The intent of this passage was to ensure that a list would be updated and published at regular intervals. When asked about the list of NIST accredited providers, Ms. Parris said that NIST will maintain an up-to-date list on their Website of those providers who voluntarily provide contact information to be posted. This list will be updated regularly and will be considered the most current source for information. The second sentence now says that the list will be published "as specified in Appendix D."

Section 2.3.7 also stated that the PTOB/PTPA would publish a list of PT fields of testing. However, Section 2.3.2.1 says that NELAC is responsible for this. The last sentence of 2.3.7 has been deleted.

Other Changes

In the first sentence of **Section 2.2.3**, "become accredited" was changed to "obtain or maintain accreditation." The last sentence in Section 2.2.3 was moved to the end of **Section 2.2.4**.

Chapter 2, Sections 2.4 - 2.7 (Darlene Raiford and Michele Kropilak)

Frequency Issue

Section 2.4.1 states that "each laboratory shall participate in at least two PT studies per year unless a different frequency for a given program is defined in the Appendices." The Virginia NELAC Workgroup commented that they are currently only required to participate in one PT study per year under the Clean Water Act or Safe Drinking Water Act. Therefore, this requirement results in additional labor and cost to laboratories.

The PT Committee has discussed this frequency issue previously. The frequency of twice per year was decided on for a number of reasons. The goal was to find the minimal number of PTs that will protect public health. EPA currently requires only one PT study per year for Water Supply (WS) studies. The committee believes that a frequency of once per year does not generate enough data to adequately assess a laboratory's capability to produce quality data. In addition, once per year puts too much pressure on a laboratory to succeed with that one sample. Additional pressure may result in a laboratory treating PT samples differently from environmental samples. Treating PT samples differently is a potential result which the PT committee would like to minimize, wherever possible. The committee decided that they wanted to decrease the importance of the PTs by increasing the frequency of studies. A frequency of twice per year provides more data for evaluation, and increases the quality of laboratories. Some states already require two studies per year. One of the committee's goals is to bring states up to a common level, not require particular states to lower their standards to meet NELAC. The committee took

a vote, and based on the vote, the chapter will not be changed regarding PT frequency at this time.

Analysis of PTs by "Routine" Method

One general concern that was voiced was that under the drinking water program, laboratories may have to run PT samples for all methods used to analyze self-monitoring data. The practice of requiring only the analysis of PT samples by a single method when laboratories may analyze samples and report data by multiple methods. The committee's intent in **Section 2.5** was to reduce costs for laboratories by limiting the requirement to analysis by a single method (one used routinely in their normal analyses), rather than by each method used.

Also regarding **Section 2.5**, the question was asked whether reporting averages of multiple runs, runs by more than one analyst, or other "safeguards" commonly practiced by laboratories was disallowed. Would onsite auditors check to see if PT samples are run under the exact conditions as "routine" samples? The PT Committee agreed that this issue may be better addressed within the On-Site Assessment Committee.

"Check for Error" Scoring

Section 2.6 states that "each result shall be scored on an acceptable/not acceptable basis." It was asked whether this removes the "check for error" score. There is no "check for error" scoring in NELAC. Scoring is "acceptable/not acceptable" based on acceptance limits. Mr. Graves added that although "check for error" is still in the National Standards, it is purely informational.

Additional Studies Must be Reported

The comment was received that laboratories should particularly note that they cannot **NOT** count results from extra studies. The committee agreed that this is true, and to help clarify this, modified the last sentence of **Section 2.7.3** to read, "These additional studies are not distinguished from the routinely scheduled studies; that is, they <u>shall be reported and</u> are counted and scored the same way..."

PT Study Schedule

A sentence was added to the end of **Section 2.7.6**. It reads, "The months which the accrediting authorities specify must adhere to the required semiannual schedule. If the accrediting authority does not specify the months taken then the laboratory determines the schedule."

Appendix A. PT Provider Approval Criteria (Tom Coyner)

Confidentiality of PT Study Data

The last sentence of A.6.0 was deleted.

Accountability of PT Providers/Sample Integrity

The PT Committee discussed accountability for PT providers. Specifically, what happens when a laboratory fails a PT because the sample provided to them was bad. The provider may not notify the laboratory(s) that the sample(s) was bad. Oversight was originally intended for the PTOB, but NIST cannot provide this function. Mr. Graves commented that the EPA database will provide "flags" to NIST in the form of summary statistics. A committee member commented that, even if the error were discovered, it would take time to correct the situation. Meanwhile, the laboratory could lose its accreditation.

Mr. Coyner said that NELAC accreditation is essentially a "license to do business" for commercial environmental laboratories. NIST accreditation is the same for PT providers. With the NELAC standards, providers will be expected to self-police to some extent. Because the loss of accreditation affects a laboratory's business, people will be willing to take legal action. Mr. Chuck Wibby added that the providers have an economic incentive to recognize their mistake and provide a second sample free of charge (not to validate an invalid sample).

A new **Section A.10** (Notification of Sample Integrity) has been added to accommodate the concern about the integrity of PT samples. It reads, "The provider is responsible for notifying all laboratories and primary accrediting authorities that a particular analyte was determined to not meet the requirements of Appendix B or is deemed of unacceptable quality for NELAC purposes, within 30 calendar days of each study closing date."

Appendix B. Pt Sample Design And Acceptance Guidelines (Matt Caruso)

Regression Equations

At the meeting, Mr. Caruso handed out preliminary results from the analysis of combined robust performance evaluation (PE) data. Data used in the analysis were from the NY State Dept. of Health (Matt Caruso) and Analytical Products Group (Tom Coyner). Mr. Caruso said that a minimum of six data sets were used to develop regression equations. This is historically what the EPA has used and equates with approximately three years of data. Before the committee can adopt the regression equations, Mr. Caruso's numbers will need to be compared with the criteria developed for the National Standards. The committee has not yet received this information from EPA.

It was asked whether the regression equations, and supporting data, should be published as part of the NELAC Standards. Also, whether the list of additional analytes should be published (perhaps in Chapter 1). Ms. Betsy Dutrow stated that she will present these questions to the NELAC Board of Directors and advise the committee with their response.

Reporting Formats

As a result of the discussion on state selection of PT providers (below), it was recognized that one of the problems states may face is compatibility of data formats between providers and primary accrediting authorities. The computer capabilities and resources between states vary. In

order to accommodate this variability, a new **Section B.5.3** was added. It states, "Providers shall supply summary PT data to the primary accrediting authorities, as per Section 2.6, in a format acceptable to the primary accrediting authority."

Appendix C. PT Acceptance Criteria And PT Pass/Fail Criteria (Chuck Wibby)

Interdependent Analytes

The request was made that the committee consider placing metals in the interdependent category. After consideration, The committee felt that it was not justified because metals do not act similarly within the same system.

Mr. Wibby proposed to eliminate references to interdependent analytes within Appendix C since NELAC is now accrediting on an analyte-by-analyte basis. Members of the committee objected to this.

It was proposed that for volatiles, there would be no difference between initial and ongoing accreditation. The proposal was to change the requirement for initial accreditation (currently, pass two out of three PTs, at an 80% pass rate) to make it equal to ongoing accreditation (pass two out of three PTs, at a 100% pass rate).

Mr. Wibby will reword **Section C.5.0** (NELAC PT Study Pass/Fail Criteria) to eliminate "pass/fail" language.

Appendix D. Proficiency Testing Oversight Body/Proficiency Test Provider Accreditor (Barbara Burmeister)

Comparison of Reports

Ms. Burmeister prepared a cross comparison of NELAC PT Appendix D and NIST's Handbook 150 (March 1994) and 150-XX (October 1998). Ms. Anne Rhyne will send a list of items that are in the NELAC Standard but are not in the NIST Handbook 150-XX to Mr. Doug Faison (copy to Ms. Reenie Parris).

Appendix E. Microbiology (Matt Caruso)

No discussion was needed for Appendix E at this time. No changes resulted from this meeting.

Appendix F. Radiochemistry (Chuck Wibby and Tom Coyner)

Mr. Wibby distributed a copy of EPA's *Radiochemistry National Criteria Document* (September, 1998 version). Mr Wibby suggested six minor additions that would make the document more consistent with the chemical and microbiological sections of the EPA National Standards.

EPA's National Standards are included in the NELAC Standards by reference. Mr. Wibby proposed that the PT Committee use the *Radiochemistry National Criteria Document*, and

reformat (i.e., renumber, retitle) it to work within the NELAC system, incorporating the six suggested changes. The committee agreed with his proposal. He will proceed in making the changes (highlighting them) and send the new Appendix F out to committee members for review. This appendix will be added to the agenda for open discussion at the interim meeting.

UNRESOLVED ISSUES

Should a State Choose/Limit Providers? (Tom Coyner)

Some states have requested that the NELAC Standard be changed to allow participating states to select the PT Provider(s) used in their state. The current standard allows the laboratories to select their own PT Provider, and requires the states to accept the results of all qualified PT Providers. Mr. Coyner prepared an issue paper for this discussion entitled "State Selection of PT Providers." In the paper, he described the following:

- fundamental assumptions regarding the PT program process within NELAC
- assumptions for states that wish to select the PT provider for their state
- issues that are fundamental to the NELAC process and are the result of the US EPA's and NELAC's selection of a multi-provider approach to providing a suitable PT program for a national accreditation system
- discussion of each scheme for PT providers

His conclusion was that the selection of the PT providers should be a laboratory, not a state decision.

The committee discussed pros and cons for allowing the states to choose the PT providers for their state. A member of the committee summarized the key question as: "What is the system with the greatest flexibility for the greatest number of parties?" Following discussion, the committee decided that more input was needed and agreed to add the topic to the agenda for the interim meeting.

Reevaluate Scopes of Accreditation (Chapter 1) and PT Fields of Testing (Chapter 2) (Anne Rhyne)

Scope of Accreditation (Ch. 1)	Fields of Testing (Ch. 2)
program-matrix/method/analyte	program/matrix/analyte
e.g., DW/502.2/benzene	e.g., DW/benzene

Ms. Rhyne reviewed some of the background for this issue. The EPA released a direct final rule for *National Primary and Secondary Drinking Water Regulations: Analytical Methods for Regulated Drinking Water Contaminants* on September 3, 1998 (FR Vol. 63, No. 171). In this document, the EPA says, "In the future, EPA may elect to make performance evaluation (PE) samples more challenging and lower the costs of the PE program by not including all regulated contaminants in each PE study. This would mean that a laboratory could be required to report whether or not a contaminant was detected in the PE sample and correctly report the

concentration of each contaminant that it did detect in the sample." Some committee members felt that the language was vague with respect to scope. Specifically, they questioned whether these requirements are method specific. The Federal Register also states that the EPA expects to publish its performance-based measurement systems (PBMS) implementation strategy for water programs in the Federal Register by the end of calendar year 1998. In order to help clarify some issues related to PE requirements and changes in regulation, Mr. Graves offered to contact Mr. Steve Clark, Dr. Richard Reding, and others at EPA to invite them to participate in the next PT conference call. The PT Committee decided to keep the standards as they are for now, knowing that it may change due to the Federal Register and/or PBMS.

Qualitative Analysis of PTs (Michele Kropilak)

Should the compounds, not just classes, be specified for PTs?

Ms. Nettrour will take the lead on revising section 2.3.2.1 and Mr. Wibby will revise section C.1.1.1. to reflect the changes discussed by the committee.

NIST UPDATE

During the course of the meeting, Ms. Rhyne placed a call to Ms. Reenie Parris to get an update on NIST activities. Ms. Parris said that the NIST Handbook 150-XX is being printed and will be posted in PDF format on the NIST Website. Applications to become a NELAC-accredited PT provider are expected to go out this week. Those applications which are properly completed and received by January 4, 1999 will be considered as the first class for accreditation. No date has been set for actually accrediting the first class, but at the latest, it will be June 1, 1999. Assessor training is taking place at NIST, and is being conducted by Mr. Doug Faison, Mr. Stan Rasberry, and Ms. Parris. Training topics are NVLAP, ISO 25, and Handbook 150-XX.

When asked about the list of NELAC-accredited providers, Ms. Parris said that NIST will maintain an up-to-date list on their Website (described above in discussion on Section 2.3.7).

Regarding the PT study retention time, Ms. Parris said that the three year requirement has changed to a default of five years in Handbook 150-XX. There was concern that if a provider goes out of business, then there is no way to require them to retain data and the possibility of legal ramifications should be considered.

At the end of the discussion, committee members agreed that a written letter should be sent to Mr. Faison. Items which need to be addressed: 1) the list of providers, and whether historical records will be maintained; and 2) a NIST ethics section. Ms. Rhyne agreed to write the letter. In addition, the PT committee will send the appendix on radiochemistry to Ms. Parris when it is completed.

MISCELLANEOUS

A conference call has been scheduled (tentatively) for January 5, 1999, from 1 to 3 p.m.

ACTION ITEMS PROFICIENCY TESTING COMMITTEE MEETING NOVEMBER 9-10, 1998

Item No.	Action Item	Date To Be Completed
1.	Ms. Cindy Nettrour and Mr. Chuck Wibby will draft language for Section 2.3.2.1. A copy is to be sent to Mr. Bob Graves.	December 8, 1998
2.	Mr. Tom Coyner will contact Mr. Steve Baker to see how the On-Site Assessment Committee is handling PTs ("routine" methods).	December 8, 1998
3.	Ms. Anne Rhyne will distribute to committee members the list of analytes with assigned EPA numbers (from Mr. Graves).	December 8, 1998
4.	Mr. Coyner and Mr. Wibby will work on the prioritized list of analytes (how to judge an acceptable regression).	December 8, 1998
5.	Ms. Rhyne will contact the Program Policy and Structure Committee to see about putting the prioritized list of analytes into Chapter 1.	December 8, 1998
6.	Ms. Rhyne will write a letter to Mr. Doug Faison of NIST	December 8, 1998
7.	Ms. Barbara Burmeister and Mr. Chuck Wibby will revise the material for Frequently Asked Questions (FAQs) to include the justification for two PTs per year.	Interim Meeting
8.	Mr. Graves will contact Ms. Reenie Parris about specifics for homogeneity and stability testing.	December 8, 1998
9.	Mr. Wibby will modify the <i>Radiochemistry National Criteria Document</i> and distribute it to the PT Committee for review.	Interim Meeting
10.	Mr. Wibby will revise Section C.5.0 to eliminate "pass/fail" language.	December 8, 1998
	Mr. Wibby will summarize comments and responses.	Interim Meeting 1998
12.	Mr. Graves will contact representatives from EPA and invite them to attend the next PT Committee teleconference.	

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